From: <u>Jenny Seifert</u>

To: <u>Bill Jacobs/DC/USEPA/US@EPA</u>
Cc: <u>Jennifer Gaines/DC/USEPA/US@EPA</u>

Subject: RE: Bait Station Prototype Date: 07/22/2009 04:19 PM

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My apologies Jennifer,
Thank you for all your time as well on this project! It is much appreciated.
Best.
Jenny
Jennifer J. Seifert
Manager, Regulatory Affairs
Hacco, Inc.; a Neogen Company; DBA HACCO, Inc.
Hess & Clark, Inc.
920-326-2461
920-326-5135, fax
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----Original Message----
From: Jacobs.Bill@epamail.epa.gov [mailto:Jacobs.Bill@epamail.epa.gov]
Sent: Wednesday, July 22, 2009 3:17 PM
To: Jenny Seifert
Cc: Gaines.Jennifer@epamail.epa.gov
Subject: RE: Bait Station Prototype
Thank Jennifer, too. Shortening the lid to the slide model was her
idea.
From: |
  |"Jenny Seifert" <jseifert@neogen.com>
|---->
>-----
  |Bill Jacobs/DC/USEPA/US@EPA
_______
|---->
       _____
  |07/22/2009 04:14 PM
|---->
  Subject: |
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  |RE: Bait Station Prototype
Dear Bill, Thank you for the in-depth response to our stations. I believe that you have highlighted many of the specific areas that I felt might have been of concern and with this information I believe we can bring the prototypes into a better version of themselves.
Best,
Jenny
Jennifer J. Seifert
Manager, Regulatory Affairs
Hacco, Inc.; a Neogen Company; DBA HACCO, Inc.
Hess & Clark, Inc.
920-326-2461
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--Original Message--

From: Jacobs.Bill@epamail.epa.gov [mailto:Jacobs.Bill@epamail.epa.gov] Sent: Wednesday, July 22, 2009 3:09 PM
To: Jenny Seifert To: Jenny Seifert Subject: RE: Bait Station Prototype

We have examined the two prototype mouse-sized bait stations that you submitted on April 27, 2009. For convenience, we will refer to the unit with the transparent top and the sprung slide arrangement designed to close off the bait compartment if the station is lifted as the "slide" model and to the other unit as the "all-gray" model.

In your letter, you state that you believe that both of the units would meet the "Tier II" criteria indicated in EPA's rodenticide risk mitigation decision of May, 2008. You also note that the prototypes supplied were constructed of "materials ... not as strong as the final materials" presumably to be used for production models. To qualify for Tier 2, ready-to-use rodenticide stations must be shown to resist tampering efforts by dogs and by young children in the age range use to test child-resistant packaging (42-51 months). Tier 2 stations are to be labeled for indoor use only.

As your letter of April 27, 2009, addressed each of the 8 criteria for tamper-resistant bait stations with regard to your prototypes, we follow that format in our reply.

Criterion 1

As noted below and by you, the prototypes were not constructed of strong materials. Whether weather would weaken those materials further could be discussed, but the weather-resistance criterion does not apply to Tier 2 stations because their labels prohibit outdoor use.

Criterion 2

The prototypes seemed highly unlikely to withstand efforts by children and dogs to break the stations. Although stronger materials of construction could improve this situation, especially with respect to young children, some design changes may be in order.

Applying what seemed to us to be relatively gentle forces, we broke both units at points associated with their locking mechanisms and also pushed a thumb through the top of the all-gray model at its thinnest point.

Criterion 3

Both units have locking mechanisms, but both mechanisms were compromised through our manipulations. In both cases, lifting up on the lid of the station at or slightly in front of the rodent entrances created forces sufficient to break the top of the all-gray model at its locking (screw-in) point and to separate the screw housing from the base of the slide unit. The main problem is the relatively long span between the top's rear attachment (presumably to be achieved via a "living hinge" rather than clear tape on production models) and the single locking point at the front of the station. Having two or more locking points or fully nesting the station's top into its base could address the span problem. However, the fact that the top of the unit also is the top of the rodent entrance would mean that it still would be easy to pull upward on the top of the station even if it were nested in the base elsewhere.

On the slide unit, It might be possible to shorten the length of the span between the front locking mechanism and the hinge by moving the hinge location forward by extending the dark gray portion (molded with the base) up over the top of the station and having it end above the sliding arm. At that point, the hinge could be created so only the front part of the top of the unit could be lifted. Making this alteration also would allow for strengthening the rodent entrance area and reducing the size of the opening (see below). This change also would allow you to add a solid piece of plastic over the sliding sleeve to keep in on track better when the sleeve is slid into place, thereby improving the reliability of the slide's performance. Additional locking points also could be added to the now-smaller moveable lid. With the lid no longer being above the rodent entrances, children and pets would be deprived of the ability to tug upward on the lid at the entrances. The trick to this arrangement would be to develop a top-located hinge of sufficient strength. The same type of modification also might work with the all-gray design.

The bottom-up arrangement for insertion of the screw would make it impossible to refill the units without removing them from a secured state. We note that the slide model seems intended to be used unsecured, with the slide functioning to isolate the bait compartment if the station is lifted.

Criterion 4

The baffling incorporated into the design of the all-gray model seems adequate to deny children reach-in access to bait compartments via the rodent entrance holes. On the slide model, the distance between the rodent entrance and the opening to the bait compartment is "borderline" to the distance that a CRP-aged child could reach with a finger if unable to get the whole hand into the station. The rodent entrance holes on both units seem slightly larger than would be needed to admit wild-type house mice, including pregnant females. Reducing the size of the entrances could reduce the chances of young children getting a hand into the unit. If you haven't already, you might want to try out

different entrance sizes and designs in local areas infested with house mice.

Criterion 5

The flat bottom to the all-gray model would facilitate its being secured using two-sided foam tape (which is an excellent approach to use on cleanable flat surfaces). For other surfaces, an arrangement to screw or bolt the station to a substrate could be incorporated to the design, but that arrangement would have to pass completely through the station if its up-from-the-bottom locking arrangement is retained.

The slide model seems designed not to be secured, with the slide mechanism closing off the bait compartment if the unit is lifted. That mechanism worked inconsistently in the prototype that we received. Often, the mechanism functioned as intended, but it sometimes took several attempts to set it. If a solid set was achieved, it sometimes was possible to lift the station and turn or even shake the station without releasing the slide.

Criterion 6

You indicate that the bait blocks that are to be used in these units are to be designed especially for them. Presumably, that means that the blocks are to be shaped so that, when fresh, they would force-fit into the compartments such that the blocks would not move about or come out if units were lifted or played with. We wondered about the objects that came in the all-gray model. It looks to us that they would hold 2 small blocks vertically if they were wedged in "diamond" fashion into the base of the bait compartment.

The raised lip at the base of the entrance to the bait compartment in each of the units would seem to aid in retaining bait within the compartment, unless the bait block were wedged into the unit such that it loomed directly above the lip. The lips at the bases of the rodent entrances are very low and seem unlikely to be of much help in reducing spillage or tracking out of bait that reaches the rodent passage way.

Criterion 7

The all-gray unit seems to be drab enough in color so as not to stand out from other objects, although its shape might be somewhat intriguing to children. If discovered, the slide mechanism on the slide unit might be a fun thing for a child to fiddle with. The slide should be relatively inconspicuous when units are properly placed into use, but unsecured bait stations will be move around though normal household activities, including cleaning among others.

Criterion 8

The tops of both units present ample space for presenting precautionary text.

For these units to have any hope of passing resistance trials with children and dogs, they must be made much stronger than they now are; and several of the additional improvements suggested above likely will be needed. Even so, it might be difficult for the stations to pass the dog test as unsecured units could be chomped down upon with considerable force. Tier 3 might be a more realistic target for these stations.

Bill Jacobs

Jennifer Gaines

	> From: >
-	"Jenny Seifert" <jseifert@neogen.com></jseifert@neogen.com>
-	To:
_]	Bill Jacobs/DC/USEPA/US@EPA
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_	07/21/2009 02:16 PM
> -	